

AMENDMENTS TO THE SPECIFICATION:

At page 10, lines 8 – 26, please replace the paragraph as follows (underlined denotes replacements/additions and strikethrough/double bracket denotes deletions):

Various embodiments may also include one or more non-electrophysiologic sensors for sensing cardiac or cardiac related activity, or sensors for sensing other physiologic conditions. Such non-electrophysiologic sensors may include, for example, optical blood sensors (oximetry sensors and/or photoplethysmographic sensors), accelerometers, transthoracic impedance sensors, pressure sensors, ultrasonic sensors, and temperatures sensors, among others. These sensors may be implantable, external, or partially implantable in the body. Such sensors may be employed to enhance or verify assessment and detection of a cardiac signal in the presence of noise or electrocardiographic artifacts, and/or to enhance detection and discrimination of cardiac arrhythmias. Embodiments of the present invention may incorporate one or more features disclosed in commonly owned, co-pending U.S. Patent Application 10/784,478 filed February 23, 2004, now U.S. Publication No. 2005/0119708 and in ~~[[US]]~~U.S. Patent Application Nos. 10/804,471, filed March 19, 2004, now U.S. Publication No. 2004/0230129 ~~[Attorney Docket GUID-608PA]~~; ~~[[US]]~~U.S. Patent Application No. 10/816,464, ~~entitled “Subcutaneous Cardiac Stimulation System with Patient Activity Sensing,”~~ filed April 1, 2004, now U.S. Publication No. 2004/0220633 ~~under Attorney Docket GUID-610PA~~; and ~~[[US]]~~U.S. Patent Application No. 10/817,749, ~~entitled “Subcutaneous Cardiac Sensing and Stimulation System Employing Blood Sensor,”~~ filed April 2, 2004, now U.S. Publication No. 2004/0220629 ~~under Attorney Docket GUID-613PA~~, and in U.S. Patent Nos. 6,409,675; 6,415,174; 6,480,733; and 6,491,639, all of which are hereby incorporated herein by reference in their respective entireties.

At page 12, lines 3 – 19, please replace the paragraph as follows (underlined denotes replacements/additions and strikethrough/double bracket denotes deletions):

In another implementation, the ITCS device may include one or more leads incorporating electrodes configured for positioning in direct contact with the heart, great vessel or coronary vasculature, such as via one or more leads implanted by use of conventional transvenous or epicardial delivery approaches. An ITCS device of this configuration may be viewed as a hybrid system that is capable of operating in numerous modes, including intrathoracic modes, subcutaneous non-intrathoracic modes, or a combination of these modes (operating in parallel or sequentially). In general, an ITCS device employing intrathoracic leads/electrodes may perform a variety of sensing, detection, diagnostics, and therapy operations using intrathoracic electrodes, subcutaneous non-intrathoracic electrodes, or a combination of these electrodes. Inclusion of intrathoracic electrodes may provide for enhanced cardiac management features, including monitoring, pacing, defibrillation, resynchronization, and sub-threshold stimulation features. An ITCS device implemented according to this approach may incorporate structures and functions disclosed in commonly owned, co-pending U.S. Patent Application Serial No. 10/462,001 filed June 13, 2003, now U.S. Publication No. 2004/0230229 and in [[US]]U.S. Patent [[Nos]]No. 5,331,966, which are hereby incorporated herein by reference.

At page 12, lines 20 – 27, continuing onto page 13, lines 1 – 9, please replace the paragraph as follows (underlined denotes replacements/additions and strikethrough/double bracket denotes deletions):

By way of example, an ITCS device employing one or more intrathoracic leads/electrodes may be configured to provide multichamber or multisite pacing for treatment of contractile dysfunction, while concurrently treating bradycardia and tachycardia. An ITCS device of this configuration can operate as a cardiac function management device, or CFM device, to improve pumping function by altering heart chamber contraction sequences while maintaining pumping rate and rhythm. Various ITCS device embodiments described herein may be used in connection with congestive heart failure monitoring, diagnosis, and/or therapy. Methods, structures, and/or techniques directed to CHF treatment, such as those involving dual-chamber or bi-ventricular pacing/therapy, cardiac resynchronization therapy, cardiac function optimization, or other CHF related methodologies, can be incorporated in an ITCS device of the present invention and include features of one or more of the following references: commonly owned ~~US Pat. App. S/N~~U.S. Patent Application No. 10/270,035, filed October 11, 2002, now U.S. Publication No. 2003/0130702 ~~entitled “Timing Cycles for Synchronized Multisite Cardiac Pacing;”~~ and ~~[[US]]~~U.S. Patent Nos. 6,411,848; 6,285,907; 4,928,688; 6,459,929; 5,334,222; 6,026,320; 6,371,922; 6,597,951; 6,424,865; and 6,542,775, each of which is hereby incorporated herein by reference.

At page 13, lines 10 – 26, continuing onto page 14, lines 1 – 2, please replace the paragraph as follows (underlined denotes replacements/additions and strikethrough/double bracket denotes deletions):

An ITCS device employing one or more intrathoracic leads/electrodes may be configured to provide a rate smoothing or regularization pacing therapy. Rate smoothing provides a measure of control over the rate of change of the ventricular pacing rate. According to one approach, the rate of change of the ventricular pacing rate is preferably controlled on a cycle-to-cycle basis so as to maintain the rate of change within a programmed percentage of the previous cycle's rate. This function is achieved via the comparison of the ventricular pacing rate for each cycle to a "rate window" or percentage of the period for the previous cardiac cycle so as to ensure that the period of the pacing pulses is constrained from cycle to cycle by the limits defined by the rate window. Controlling when and under what cardiac conditions to turn on/off or adjust the parameters for a rate smoothing program may be highly advantageous. This control allows the rate smoothing to be deactivated when use of rate smoothing would be detrimental, or constraining, to a patient's need for rapid heart rate acceleration or deceleration. Furthermore, by selectively turning rate smoothing off or adjusting rate smoothing parameters, the number of pacing pulses delivered to a patient may be reduced. Exemplary structures and methods for implementing a rate smoothing pacing therapy in an ITCS device of the present invention are disclosed in commonly owned [[US]]U.S. Patent No. 6,501,987, which is hereby incorporated herein by reference.

At page 15, lines 1 – 11, please replace the paragraph as follows (underlined denotes replacements/additions and strikethrough/double bracket denotes deletions):

In a further implementation, one or more subcutaneous electrode subsystems or electrode arrays may be used to sense cardiac activity and deliver cardiac stimulation energy in an ITCS device configuration employing an active can or a configuration employing a non-active can. Electrodes may be situated at anterior and/or posterior locations relative to the heart. Examples of useful subcutaneous electrodes, electrode arrays, and orientations of same are described in commonly owned ~~[[US]]~~U.S. Patent Application Serial No. 10/738,608 ~~entitled “Noise Canceling Cardiac Electrodes,”~~ filed December 17, 2003, now U.S. Publication No. 2004/0230243, and ~~[[US]]~~U.S. Patent Application Serial No. 10/465,520 filed June 19, 2003, now U.S. Publication No. 2004/0230230, ~~entitled “Methods And Systems Involving Subcutaneous Electrode Positioning Relative To A Heart”,~~ which are hereby incorporated herein by reference.

At page 15, lines 12 – 22, please replace the paragraph as follows (underlined denotes replacements/additions and strikethrough/double bracket denotes deletions):

Certain configurations illustrated herein are generally described as capable of implementing various functions traditionally performed by an implantable cardioverter/defibrillator (ICD), and may operate in numerous cardioversion/defibrillation modes as are known in the art. Exemplary ICD circuitry, structures and functionality, aspects of which may be incorporated in an ITCS device of a type described herein (e.g., a purely subcutaneous implementation or a hybrid implementation), are disclosed in commonly owned U.S. Patent Nos. 5,133,353; 5,179,945; 5,314,459; 5,318,597; 5,331,966; 5,620,466; 5,662,688, and 6,522,915, and in ~~[[US]]~~U.S. ~~Published~~ Patent Application ~~2002/0107544,~~ Serial No. 10/011506, filed November 5, 2001, now U.S. Publication No. 2002/0107544, ~~each of which is hereby incorporated herein by reference.~~ which are hereby incorporated herein by reference in their respective entireties.

At page 22, lines 20 – 27, continuing into page 23, lines 1 – 9, please replace the paragraph as follows (underlined denotes replacements/additions and strikethrough/double bracket denotes deletions):

According to a configuration that provides cardioversion and defibrillation therapies, the control system 205 processes cardiac signal data received from the detection circuitry 202 and initiates appropriate tachyarrhythmia therapies to terminate cardiac arrhythmic episodes and return the heart to normal sinus rhythm. The control system 205 is coupled to shock therapy circuitry 216. The shock therapy circuitry 216 is coupled to the subcutaneous electrode(s) 214 and the can or indifferent electrode 207 of the ITCS device housing. Upon command, the shock therapy circuitry 216 delivers cardioversion and defibrillation stimulation energy to the heart in accordance with a selected cardioversion or defibrillation therapy. In a less sophisticated configuration, the shock therapy circuitry 216 is controlled to deliver defibrillation therapies, in contrast to a configuration that provides for delivery of both cardioversion and defibrillation therapies. Exemplary ICD high energy delivery circuitry, structures and functionality, aspects of which may be incorporated in an ITCS device of a type described herein are disclosed in commonly owned U.S. Patent Nos. 5,372,606; 5,411,525; 5,468,254; and 5,634,938, and in ~~US Published~~ U.S. Patent Application ~~2002/0107548, serial no. 011947~~ Serial No. 10/011,947, filed November 5, 2001, now U.S. Patent No. 7,039,459, which are hereby incorporated herein by reference in their respective entireties.

At page 28, lines 7 – 18, please replace the paragraph as follows (underlined denotes replacements/additions and strikethrough/double bracket denotes deletions):

In one configuration, an ITCS device includes a pulse generator and one or more electrodes that are implanted subcutaneously in the chest region of the body, such as in the anterior thoracic region of the body. The ITCS device may be used to provide atrial and/or ventricular therapy for bradycardia, tachycardia, and asystole. Tachyarrhythmia therapy may include cardioversion, defibrillation, and anti-tachycardia pacing (ATP), for example, to treat atrial or ventricular tachycardia or fibrillation. Bradycardia therapy may include one or more known bradycardia pacing therapies. Methods and systems for implementing asystole prevention therapy that are particularly well suited for subcutaneous applications are described in commonly owned U.S. Patent Application, ~~entitled “Subcutaneous Cardiac Stimulator Employing Post-Shock Transthoracic Asystole Prevention Pacing,”~~ Serial Number 10/377,274, filed on February 28, 2003, now U.S. Publication No. 2004/0172066, which is incorporated herein by reference in its entirety.

At page 30, lines 3 – 17, please replace the paragraph as follows (underlined denotes replacements/additions and strikethrough/double bracket denotes deletions):

The ITCS device may be used within the structure of an advanced patient management (APM) system. Advanced patient management systems may allow physicians to remotely and automatically monitor cardiac and respiratory functions, as well as other patient conditions. In one example, implantable cardiac rhythm management systems, such as cardiac pacemakers, defibrillators, and resynchronization devices, may be equipped with various telecommunications and information technologies that enable real-time data collection, diagnosis, and treatment of the patient. Various embodiments described herein may be used in connection with advanced patient management. Methods, structures, and/or techniques described herein, which may be adapted to provide for remote patient/device monitoring, diagnosis, therapy, or other APM related methodologies, may incorporate features of one or more of the following references: ~~US~~U.S. Patent Nos. 6,221,011; 6,270,457; 6,277,072; 6,280,380; 6,312,378; 6,336,903; 6,358,203; 6,368,284; 6,398,728; and 6,440,066, which are hereby incorporated herein by reference.

At page 33, lines 3 – 17, please replace the paragraph as follows (underlined denotes replacements/additions and strikethrough/double bracket denotes deletions):

In one example arrangement, the volume including a majority of ventricular tissue may be associated with a cross sectional area bounded by lines or planes defined between the ends of the electrode subsystems 502, 504 or between active elements of the electrode subsystems 502, 504. In one implementation, the planes defined between active elements of the electrode subsystems 502, 504 may include a medial edge and a lateral edge of the can electrode 502, and a proximal end and a distal end of a coil electrode utilized within the second electrode subsystem 504. Arranging the electrode subsystems so that a majority of ventricular tissue is contained within a volume defined between the active elements of the electrode subsystems 502, 504 provides an efficient position for defibrillation by increasing the voltage gradient in the ventricles of the heart 510 for a given applied voltage between electrode subsystems 502, 504. Additional details concerning subcutaneous electrode positioning according to embodiments of the present invention are disclosed in previously incorporated US Patent Application Serial No. 10/465,520, filed June 19, 2003, now U.S. Publication No. 2004/0230230.

At page 39, lines 14 – 22, please replace the paragraph as follows (underlined denotes replacements/additions and strikethrough/double bracket denotes deletions):

An audio output device 914 may also be coupled to the cardiac therapy device 910. Heart sounds may, for example, be broadcast to the patient, care-giver or physician via the audio output device 914. By way of example, heart sounds and cardiac electrophysiologic data may be broadcast and presented to the patient, care-giver or physician via the audio output device 914 and display 912 in accordance with the approaches described in commonly owned, co-pending U.S. Patent Application No. 10/801,139, entitled ~~“Implantable Device with Cardiac Event Audio Playback,”~~ filed March 15, 2004 ~~under Attorney Docket GUID-609PA,~~ now U.S. Publication No. 2004/0230249, which is hereby incorporated herein by reference.

At page 39, lines 23-27, continuing onto page 40, lines 1-8, please replace the paragraph as follows (underlined denotes replacements/additions and strikethrough/double bracket denotes deletions):

The external components of the system 900 may also include a user interface 916, which may take on a variety of forms. The user interface 916 may be implemented to have varying complexity, ranging from relatively complex capabilities (e.g., a programmer) to relatively simple capabilities (e.g., a bed-side console or patient activator device). The user interface 916 permits the patient, care-giver or physician to communicate, interrogate, and/or interact with the cardiac therapy device 910, depending on the sophistication of the user interface 916. For example, the user interface 916 may allow the patient to initiate recording of cardiac activity, much in the way of a loop recorder. Details of useful heart activity recording techniques are disclosed in commonly owned, co-pending U.S. Patent Application 10/785,431 filed February 24, 2004, now U.S. Publication No. 2005/0004615, which is hereby incorporated herein by reference. By way of further example, a physician may interrogate and/or program the cardiac therapy device 910 via the user interface 916.